REMARKS

The Office Action mailed on November 25, 2008 has been reviewed and the comments of the Examiner carefully considered. Claims 1-8 are pending and currently stand rejected.

Rejections under 35 U.S.C. § 103

Claims 1-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cheong (US 6,326,410) in view of Webster (US 4,664,662). Regarding independent claim 1, the Examiner alleged that although Cheong does not explicitly teach treating the foamed product with a dispersion of therapeutic agent prior to drying, Cheong contemplates such treatment by teaching that "the foams of the invention may also include topical medicaments and antiseptics…as well as other therapeutically useful additives" (col. 3, line 65 – col. 4, line 3). Further, the Examiner alleged that treatment of polyurethane foams with therapeutic agents is well-known in the art as Webster teaches polyurethane foam wound dressings may contain therapeutic agents and that "[t]he physiologically active component may be incorporated into the foam during the process for manufacturing the foam or just prior to use by soaking in a solution of the components" (col. 8, lines 8-11). Thus, the Examiner alleged that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to treat the polyurethane foams of Cheong with a dispersion of a therapeutic agent per the teachings of Webster to provide a polyurethane wound dressing material with a therapeutic agent. Applicants respectfully disagree.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all claim limitations. MPEP § 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Applicants respectfully submit that neither Cheong nor Webster, alone or in combination, teaches, suggests, or otherwise discloses all limitations of the instant invention. Applicants' independent claim 1 discloses:

> "A method of forming a polyurethane foam suitable for use as a wound-contacting layer, said method comprising: mixing 1 part by weight of an isocyante-capped prepolymer having from 0.5 to 1.2 meq NCO groups/g with from 0.4 to 1.0 parts by weight of water in the presence of from 0.05 to 0.4 parts by weight of a C1 to C3 monohydric alcohol to form a foamed product; ***followed by treating the foamed product with a dispersion of a therapeutic agent and drying the treated foamed product***" (emphasis added).

Regarding Cheong, as the Examiner admitted, "Cheong does not explicitly teach treating the foamed product with a dispersion of therapeutic agent prior to drying".

Webster cannot cure the deficiencies of Cheong. Webster discloses a foam wherein the "physiologically active component may be *incorporated into the foam during the process of manufacturing the foam* **or** *just prior to use by soaking* in a solution of the components" (emphasis added). In contrast, the loading of the therapeutic agent onto the foamed products of applicants' instant invention occurs between the two time periods disclosed in Webster – *i.e.*, after the process manufacturing the foam has been completed and before the product has been packaged and shipped for use. Thus, even if the cited references were combined in the manner suggested by the Examiner, one of ordinary skill in the art would not arrive at the claimed treated foamed product.

The foamed product of applicants' instant invention is treated post-manufacturing by a dispersion of a therapeutic agent, dried, and subsequently packaged and shipped for use. Thus,Webster does not teach, suggest, or otherwise disclose the claimed method of "treating the foamed product with a dispersion of a therapeutic agent and drying the treated foamed product" (emphasis added).

It is because the method of the instant invention comprises treating the foamed product with a dispersion of a therapeutic agent and drying – *i.e.*, oven drying or freeze drying – the treated foamed product that the polyurethane foams of the instant invention exhibit, surprisingly

and unexpectedly, sustained release behavior superior to that of polyurethane foams that have been medicated by incorporating the medicament into the foaming polyurethane mixture (*see, e.g.*, page 2, lines 16-22; page 9, lines 16-19; page 10, lines 8-14; **Figure 1**).

Procedure 1 and **Figure 1** of the instant specification illustrate one example wherein the sustained release of chlorhexidine gluconate (CHG) from the oven-dried and freeze-dried post-treated foamed materials of applicants' instant invention was compared to medicated foams made by incorporating CHG into the reaction mixture, and can be seen to provide a manifold sustained release of the CHG using UV/Visible spectrophotometer. At 25 hours, for example, the oven-dried and freeze-dried post-treated foamed materials of applicants' instant invention contain, respectively, approximately 9 mg/ml and 8.5 mg/ml of chlorhexidine compared to the 3.5 mg/ml of the prior art medicated foams. Even more surprising and unexpected, at 75 and 225 hours, the post-treated foamed materials of applicants' instant invention still contain approximately 4.5 mg/ml of the therapeutic agent while the prior art foams only contain less than 1 mg/ml. This clearly indicates superior sustained release behavior.

As neither Cheong nor Webster, alone or in combination, discloses the claimed method of forming a polyurethane foam wherein the polyurethane foam is treated with a dispersion of a therapeutic agent after forming the foam and then followed by drying, applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 2-8 are thereby allowable as written as depending from an allowable independent claim.

VIA ELECTRONIC FILING

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5337 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5037) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

DEBORAH ADDISON ET AL.

Date: April 23, 2009

By: /Christopher I. Halliday/

Christopher I. Halliday
Registration No. **42,621**

MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5337
Facsimile: (215) 963-5001
E-Mail: challiday@morganlewis.com